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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,206	10/26/2000	Daniel E.H. Afar	G&C 129.21-US-U1	3714

22462 7590 12/10/2001

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED: 12/10/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/697,206

Applicant(s)  
Afar et al

Examiner  
MINH TAM DAVIS

Art Unit  
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 12, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-43 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 37, drawn to polynucleotide encoding 20P2H8 polypeptide, fragments thereof, an expression vector containing said polynucleotide, a host cell that contains an expression vector, a process for producing a 20P2H8 polypeptide, and a pharmaceutical composition comprising an antisense polynucleotide, classified in class 536, subclass 23.1.

II. Claims 10-12, 35, 41, drawn to 20P2H8 polypeptide, fragment thereof, and a vaccine composition comprising an immunogenic portion of 20P2H8 polypeptide, classified in class 530, subclass 350.

III. Claims 13-21, 23-24, 38, drawn to an antibody or fragment thereof that specifically binds to 20P2H8 polypeptide, and the antigenic binding region of said antibody, classified in class 530, subclass 387.1.

IV. Claim 22, drawn to a transgenic animal, classified in class 800, subclass 2.

V. Claim 25, 36, drawn to a vector comprising a polynucleotide encoding a single chain antibody that specifically binds to 20P2H8 polypeptide, classified in class 435, subclass 252.3.

VI. Claim 26, drawn to an assay for detecting the presence of 20P2H8 polypeptide, using an antibody, classified in class 435, subclass 7.1.

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VII. Claim 27, drawn to an assay for detecting the presence of 20P2H8 polynucleotide, using a hybridization probe, classified in class 435, subclass 6.

VIII. Claim 28, drawn to an assay for detecting the presence of 20P2H8 polynucleotide, by amplifying 20P2H8 polynucleotide, classified in class 435, subclass 91.2.

IX. Claim 29, drawn to a method for detection of dysregulated cellular growth, by detecting the alterations in the status of 20P2H8 gene, classified in class 435, subclass 6.

X. Claims 30, 32, 34, drawn to a method for detection of neoplasm, by measuring the expression of 20P2H8 polynucleotide, or 20P2H8 RNA level, classified in class 435, subclass 6.

XI. Claims 29, 31, drawn to a method for detection of dysregulated cellular growth, or monitoring 20P2H8 gene product, by detecting the alterations in the status of 20P2H8 gene product, classified in class 435, subclass 7.1.

XII. Claim 33, drawn to a method for detection of neoplasm, by measuring the level of 20P2H8 polypeptide, classified in class 435, subclass 7.1

XIII. Claim 37, drawn to a ribozyme, classified in class 530, subclass 350.

XIV. Claim 39, drawn to a method of treating cancer, comprising administering a vector comprising a polynucleotide encoding a single chain antibody that specifically binds to 20P2H8 polypeptide, classified in class 514, subclass 44.

XV. Claim 40, 42, drawn to a method for treating cancer or inhibiting the development of cancer, comprising administering an antisense, classified in class 514, subclass 44.

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XVI. Claim 40, 42, drawn to a method for treating cancer or inhibiting the development of cancer, comprising administering a ribozyme, classified in class 514, subclass 2.

XVII. Claim 43, drawn to a method of identifying a molecule that modulates a biological activity of 20P2H8, classified in class 435, subclass 4..

In addition, upon the election of group I , further election of the following patentably distinct species of the claimed invention is required:

Full length sequence or fragments thereof.

Upon the election of the species fragments , further election of the following patentably distinct species of the claimed invention is required:

Any one of the fragments recited in claims 1, 3, and 4.

Upon the election of group III , further election of the following patentably distinct species of the claimed invention is required:

Any one of the markers recited in claim 17.

Upon the election of any one of groups X, XIV-XVI, further election of the following patentably distinct species of the claimed invention is required:

Any one of the cancer recited in claim 34.

Upon the election of group XV, XVI, further election of the following patentably distinct species of the claimed invention is required:

A method for treating cancer or inhibiting the development of cancer.

2. The inventions are distinct, each from each other because of the following reasons:

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Inventions (I-V, XIII) and (VI-XII, XIV-XVII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h)). In this instant case, a polypeptide could be used for several purposes, e.g. for biochemical assay, for making antibodies, and for making an affinity column to purify its antibodies; a DNA sequence could be used for the detection of similar DNA or RNA sequences, for making an expression vector, and for producing its encoded protein; an antibody could be used for immunoassay, for purification of its antigen, and for detection of diseases; a transgenic animal could be used for screening and testing drugs, for *in vivo* production of antibodies, for treating diseases.

The products of groups I-V, XIII are patentably distinct, because they are drawn to entirely different biochemicals or animals, having different structures and/or biological properties.

The methods of groups VI-XII, XIV-XVII are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species full length sequence or fragments thereof are distinct because they are structurally distinct.

The species markers are distinct because they have different properties.

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The species cancer are distinct because they are different types of cancer, with different etiology.

The species treating cancer and inhibiting development of cancer are distinct, because a treated cancer does not necessarily mean that the development of said cancer, i.e. carcinogenesis, is inhibited.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

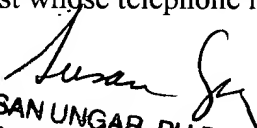
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

November 2, 2001

  
SUSAN UNGAR, PH.D  
PRIMARY EXAMINER